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ODWALLA, INC. and THE COCA-COLA COMPANY

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

ROBIN REESE, individually and on behalf
of all others similarly situated,

Plaintiff,

vs.

ODWALLA, INC. and THE COCA-COLA
COMPANY,

Defendants.

Case No. 3:13-CV-00947-YGR

**NOTICE OF MOTION AND MOTION;
MEMORANDUM OF LAW IN SUPPORT
OF DEFENDANTS' MOTION TO DISMISS**

Judge: Hon. Yvonne Gonzalez Rogers

Complaint Filed: March 1, 2013
Hearing Date: September 27, 2016
Hearing Time: 2:00pm
Courtroom: 1, 4th Floor

NOTICE OF MOTION AND MOTION

TO PLAINTIFF AND PLAINTIFF'S ATTORNEY OF RECORD:

PLEASE TAKE NOTICE THAT on September 27, 2016, at 2:00pm, or as soon thereafter as this may be heard, in Courtroom 1, 4th floor of this Court, located at 1301 Clay Street, Oakland, CA 94612, before the Honorable Yvonne Gonzalez Rogers, defendants the Coca-Cola Company and Odwalla, Inc. (collectively, "Odwalla") will and hereby do move the Court for an order dismissing Plaintiff's Complaint and each claim therein filed by plaintiff Robin Reese.

This motion is made pursuant to Federal Rule of Civil Procedure 12(b)(6), and is based on the following grounds:

1. Plaintiff's claims, which are based on events that predate the May 25, 2016 publication of the U.S. Food and Drug Administration's final Guidance for Industry: Ingredients Declared as Evaporated Cane Juice, Dkt. No. FDA-2009-D-0430, fail to allege a violation of California's Sherman Food, Drug and Cosmetic Law, Cal. Health & Saf. Code §§ 109875 *et seq.*

2. Plaintiff's claims are expressly preempted by the federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 *et seq.* because, at the time of her purchases, federal law was unsettled and did not expressly prohibit the term evaporated cane juice, or require that this ingredient be labeled as something else.

3. Plaintiff's claims for injunctive relief are moot because Odwalla no longer labels any of its products as containing evaporated cane juice.

This motion is based on this notice of motion, prior findings by the Court in this case, the accompanying memorandum of points and authorities, all pleadings and documents on file in this case, matters subject to judicial notice, and on such other written and oral argument as may be presented to the Court.

1 DATE: August 10, 2016

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/s/ Steven A. Zalesin

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STATEMENT OF ISSUES

1
2 1. Does California law authorize a private party to enforce a non-final, non-binding
3 draft FDA guidance on food labeling when, according to the plain text of the applicable statute,
4 California law incorporates only final, binding FDA regulations?

5 2. Are Plaintiff's state-law claims, which seek to impose food labeling requirements
6 before they were finalized by FDA, expressly preempted by the federal Food Drug and Cosmetic
7 Act?

8 3. Is Plaintiff's request for injunctive relief moot in light of the fact that Odwalla no
9 longer labels any products as containing evaporated cane juice?
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INTRODUCTION AND SUMMARY OF ARGUMENT

Plaintiff Robin Reese filed this case in March 2013. In her complaint, Plaintiff alleged that the labels for certain Odwalla® brand beverages and snack bars violated the federal Food Drug and Cosmetic Act (“FDCA”) and California law because they listed evaporated cane juice (“ECJ”) as an ingredient. Plaintiff premised her allegations on a non-binding, draft guidance on ECJ published by FDA in 2009. *See* Guidance for Industry: Ingredients Declared as Evaporated Cane Juice (hereinafter, “2009 Draft Guidance”).

Odwalla moved to dismiss Plaintiff’s complaint in June 2013. In its original motion, Odwalla demonstrated that Plaintiff failed to state a claim for three principal reasons:

- **First**, Plaintiff bases her claims on California’s Sherman Law, which makes FDCA requirements and FDA regulations concerning food labels the law of that state. The Sherman Law, however, only incorporates into California law final, binding requirements of federal law. The 2009 Draft Guidance was not a final or binding federal requirement.
- **Second**, Plaintiff is expressly preempted from using state law to impose requirements for food and beverage labels that differ from the requirements of federal law. Plaintiff alleges that she purchased Odwalla products labeled with ECJ prior to 2014, but federal law at that time did not prohibit ECJ labeling or require this ingredient to be labeled as something else. Plaintiff is preempted from seeking to impose a requirement under state law that federal law did not impose.
- **Third**, Plaintiff’s claims usurped FDA’s primary jurisdiction. FDA has primary jurisdiction over food and beverage labels, and the agency was engaged in an ongoing regulatory process to determine ECJ’s common and usual name.

However, before the Court had an opportunity to rule, FDA reopened its regulatory process concerning ECJ and publicly reaffirmed that the Agency had “not reached a final

1 decision on the common or usual name for this ingredient.” *See* Notice; Reopening of Comment
2 Period; Request for Comments, Data, and Information, 79 Fed. Reg. 12507 (March 5, 2014)
3 (hereinafter, the “Notice”).

4 In light of FDA’s decision to reopen its regulatory process, the Court granted Odwalla’s
5 motion to dismiss on primary jurisdiction grounds. The Court recognized that, at the time of its
6 ruling, federal law concerning ECJ remained “unsettled,” “non-binding,” and “not legally
7 enforceable.” *Reese v. Odwalla, Inc.*, 30 F. Supp. 3d 935, 939 (N.D. Cal. 2014). But rather than
8 dismiss the complaint at that time, the Court stayed the case pending the outcome of FDA’s
9 regulatory process. The Court did not reach any of the other grounds for dismissal that Odwalla
10 had advanced in its motion.

11 Given the uncertain status of ECJ under federal law, Odwalla discontinued its ECJ
12 labeling in 2014 and notified FDA of that decision. Odwalla then brought this development to
13 the Court’s attention in May 2015 when Plaintiff asked the Court to lift the stay before FDA had
14 concluded its regulatory process. The Court denied Plaintiff’s request, finding that Odwalla’s
15 “previous removal of the term ‘evaporated cane juice’ from [its] product labels” negated any
16 potential for prejudice in maintaining a stay. *See* Order, *Reese v. Odwalla, Inc.*, Dkt. No. 72
17 (June 23, 2015).

18 FDA completed its regulatory process in May 2016. *See* Revised Guidance for Industry:
19 Ingredients Declared as Evaporated Cane Juice (hereinafter “2016 Final Guidance”). In the 2016
20 Final Guidance, FDA advised that, based upon its review of the public comments, ECJ will not
21 be considered an appropriate common and usual name under federal law, and advised
22 manufacturers to identify this ingredient on labels by a different name. By that time, no Odwalla
23 products had been labeled with ECJ for more than a year.

24 The Court lifted the stay in July 2016 at the request of both parties, and Plaintiff’s
25 Complaint is now ripe for dismissal. The Court has already found that when Plaintiff purchased
26 Odwalla products labeled with ECJ, the requirements of federal law were unsettled, and that
27 FDA’s 2009 Draft Guidance was non-binding and not legally enforceable. These findings lead
28

1 inexorably to the conclusion that Plaintiff's claims are barred. California's Sherman Law
 2 incorporates only final, binding requirements of federal law, and the FDCA expressly preempts
 3 Plaintiff from attempting to create binding requirements under state law that federal law did not
 4 impose at the time of her purchases.

5 The 2016 Final Guidance does not change this analysis. Whether the 2016 Final
 6 Guidance creates a binding federal prohibition against ECJ is a novel legal question, but that
 7 issue need not be resolved in this case. The dispositive question here is: Did federal law
 8 conclusively prohibit ECJ labeling, or require this ingredient to be labeled as something else, at
 9 the time Plaintiff made her purchases? It did not, and courts have held that, even if FDA
 10 subsequently clarifies its interpretation of federal law, a prior purchaser cannot retroactively
 11 enforce such requirements without violating Due Process and running afoul of the FDCA's
 12 preemption clause. *See Wilson v. Frito-Lay N. Am.*, 961 F. Supp. 2d 1134, 1147 (N.D. Cal.
 13 2013); *Peterson v. Conagra Foods, Inc.*, No. 13-cv-3158-L (NLS), 2014 U.S. Dist. LEXIS
 14 104073, at *12 (S.D. Cal. July 29, 2014); *Eckler v. Neutrogena Corp.*, 238 Cal. App. 4th 433,
 15 189 Cal. Rptr. 3d 339 (2015).

16 For all of these reasons, Plaintiff's claims—including her claim for injunctive relief—
 17 should now be dismissed with prejudice. Odwalla discontinued its ECJ labeling in 2014, and in
 18 light of the 2016 Final Guidance, there is no prospect that Odwalla will bring that labeling back.
 19 Consequently, Plaintiff is at no risk of future harm, and her request to enjoin Odwalla from
 20 labeling its products with ECJ is moot.¹

21 **BACKGROUND**

22 **A. Odwalla**

23 Odwalla sells more than 50 varieties of Odwalla beverages and bars. Odwalla beverages
 24 come in flavors ranging from apple and carrot to "Mango Tango" and "Pomegranate Limeade."
 25

26 ¹ Copies of the 2009 Draft Guidance, the Notice, and the 2016 Final Guidance are attached as Exhibits A-
 27 C to Odwalla's accompanying Request for Judicial Notice ("RJN").

1 Odwalla bars are also available in a wide variety of flavors such as Banana Nut, Chocolate
2 Peanut Butter, and Lemon Ginger.

3 Depending upon the type of beverage or bar, Odwalla uses different sweeteners to
4 achieve the desired taste or nutritional profile. Some Odwalla products contain naturally sweet
5 fruit juice with no added sugars. Others contain one or more sweetening ingredients. Prior to
6 2014, Odwalla sold some beverages and bars labeled with ECJ. Odwalla, however, discontinued
7 its ECJ labeling in the midst of FDA's ongoing regulatory process concerning ECJ.² There are
8 no Odwalla products labeled with ECJ on the market today.

9 **B. Plaintiff's Allegations**

10 Plaintiff is a California resident who filed suit in 2013 alleging that she had purchased
11 Odwalla products labeled with ECJ. Specifically, Plaintiff purchased two Odwalla beverages
12 (Strawberry Protein Monster™ Shake and Quencher Pomegranate Limeade) and two Odwalla
13 bars (Chocolate Almond Coconut and White Chocolate Macadamia) (collectively the
14 "Products") with ECJ labeling. (Compl. ¶75.) Plaintiff purports to represent a class of
15 individuals who purchased Odwalla products labeled with ECJ in the four years prior to the
16 filing of the Complaint. (*Id.* ¶82.)

17 Plaintiff has never alleged that Odwalla concealed from her the presence of ECJ. On the
18 contrary, Plaintiff thoroughly reviewed the Products' labels, noted the presence of "evaporated
19 cane juice" in the ingredients list, and alleges to have relied on that fact in making her purchasing
20 decisions. (*Id.* ¶76.) According to Plaintiff, however, ECJ was an "unlawful and unauthorized"
21 name, and the Products were thus "misbranded" in violation of the FDCA and California's
22

23 ² Copies of the pre-2014 labels for the products that Plaintiff allegedly purchased are attached as Exhibits
24 D-G to the RJN. Copies of the current labels for these products, which do not list ECJ as an ingredient,
25 are attached as Exhibits H-K. The Court may take judicial notice of these labels because they are
26 referenced in the Complaint. *See McKinniss v. Sunny Delight Beverages Co.*, No. CV-07-02034-RKG,
27 2007 U.S. Dist. LEXIS 96108, at *9-10 n.1 (C.D. Cal. Sept. 4, 2007). Alternatively, because Odwalla's
28 discontinuation of its ECJ labeling cannot seriously be disputed, the Court may convert this motion into a
motion for summary judgment and take this fact as established. *See Valentine v. City of Concord*, No. 16-
cv-00279-MEJ, 2016 U.S. Dist. LEXIS 64382, at *12 n.3 (N.D. Cal. May 16, 2016).

1 Sherman Law. (*Id.* ¶79.) As support for her allegations, Plaintiff pointed to FDA’s 2009 Draft
 2 Guidance. (*Id.* ¶41.) This publication, according to Plaintiff, “advised the industry that the term
 3 ‘Evaporated Cane Juice’ was unlawful,” but Odwalla’s labels continued to “run afoul” of this
 4 supposed requirement. (*Id.* ¶¶44, 47.)

5 The FDCA does not provide for private rights of action. Plaintiff thus does not assert a
 6 claim under the FDCA directly, but rather on the basis of California’s Sherman Law, which
 7 makes the FDCA and its implementing regulations the law of that state. Like the FDCA,
 8 however, the Sherman Law contains no private right of action, so Plaintiff invoked California’s
 9 consumer protection statutes, which prohibit, *inter alia*, conduct that is “unlawful” under another
 10 statute or regulation.

11 Cobbling together these statutes and publications, Plaintiff alleged that Odwalla’s ECJ
 12 labels violated the 2009 Draft Guidance, and in turn violated the FDCA, and in turn violated
 13 California’s Sherman Law, and in turn gave rise to statutory claims under California’s Unfair
 14 Competition Law (“UCL”) (Cal. Bus. & Prof. Code § 17200 et seq.) (Counts I-III), California’s
 15 False Advertising Law (“FAL”) (Cal. Bus. & Prof. Code § 17500 et seq.) (Counts IV-V),
 16 California’s Consumer Legal Remedies Act (“CLRA”) (Cal. Civ. Code § 1750 et seq.) (Count
 17 VI). Plaintiff also included a common law claim for unjust enrichment/quasi-contract (Count
 18 VII).

19 **C. Odwalla’s Original Motion to Dismiss**

20 Odwalla moved to dismiss Plaintiff’s Complaint on June 3, 2013. (Dkt. No. 28.) As
 21 discussed above, Odwalla’s principal grounds for dismissal were that Plaintiff failed to state a
 22 claim under California’s Sherman Law, express preemption, and primary jurisdiction.³ In
 23 support of these arguments, Odwalla made several showings relevant to the instant motion.

24
 25 ³ Odwalla accompanied its original motion to dismiss with a motion to strike the Complaint’s nationwide
 26 class allegations and its impertinent allegations regarding a product called Fanta Orange Zero, which
 27 never was labeled with ECJ. Because Plaintiff’s claims at this point should be dismissed with prejudice,
 28 Odwalla is not renewing its motion to strike at this time, but reserves all rights on both issues.

1. FDA's position on ECJ was unsettled.

Under federal law, a common and usual name for a food or ingredient can be established in two ways. FDA may undertake a formal regulatory process and establish a common and usual name by regulation. 21 U.S.C. § 341. More frequently, a food or ingredient acquires a common and usual name through “common usage” in the marketplace. 21 C.F.R. § 102.5(d). FDA has published regulations that establish standards of identity and/or common and usual names for several sweetening ingredients, including sugar, maple syrup, lactose, and cane syrup. *See* 21 C.F.R. §§ 101.4(b)(20) *et seq.* But at the time Plaintiff purchased Odwalla products labeled with ECJ, FDA had not defined ECJ by regulation or determined that federal law prohibits that term. Indeed, thousands of food and beverage products sold in the United States identified ECJ as an ingredient on their labels.⁴

In 2009, FDA notified the public and industry that it was considering whether manufacturers should be required to identify ECJ by an alternative. (*See* RJN, Ex. A.) The 2009 Draft Guidance stated that FDA had concerns that the name “evaporated cane juice” may lead some consumers to think that products made with this ingredient contain actual “juice” and suggested that “dried cane syrup” might be a more appropriate name. *Id.* However, FDA designated the 2009 Draft Guidance as a draft “Level 1” guidance document, which is FDA’s least formal means of notifying the public of its preliminary views on a topic.

The purpose and legal status of Level 1 guidance documents are established by regulation. Such documents set forth FDA’s “initial interpretations” of statutory or regulatory requirements on “highly controversial issues.” *See* 21 C.F.R. § 10.115(c). They are used to initiate a dialogue with FDA before the Agency makes a formal determination as to the requirements of federal law.⁵ Once a draft Level 1 guidance is published, members of the public are invited to submit comments to FDA “at any time.” *See id.* § 10.115(f)(4).

⁴ See FDA, Docket Folder, Ingredients Declared as Evaporated Cane Juice, at <https://www.regulations.gov/docket?D=FDA-2009-D-0430..>

⁵ See generally FDA, Fact Sheet: FDA Good Guidance Practices, at <http://www.fda.gov/downloads/AboutFDA/Transparency/TransparencyInitiative/UCM285344.pdf> (last visited August 7, 2016)

1 FDA received comments on the 2009 Guidance from more than 50 companies, trade
2 groups, and other stakeholders. All of the comments criticized FDA's approach to ECJ for one
3 or more reasons.⁶ After receiving these comments, FDA allowed several years to lapse before
4 taking any steps to finalize the guidance.

5 **2. FDA's 2009 Draft Guidance did not create a binding federal**
6 **requirement.**

7 As the "draft" designation indicates, draft "Level 1" guidance documents such as the
8 2009 Draft Guidance are "documents that have been proposed, but FDA has not made a decision
9 as to whether the proposal will be adopted in whole, in part or not at all."⁷ As a matter of federal
10 law, such guidance documents cannot impose binding legal requirements because they are
11 published without notice or Due Process and have not been subjected to official rulemaking
12 procedures. FDA regulations make this clear:

13 Are you or FDA required to follow a guidance document?

14 No. *Guidance documents do not establish legally enforceable rights or*
15 *responsibilities.* They do not legally bind the public or FDA.

16 21 C.F.R. § 10.115(d). An FDA employee who treats a draft guidance document as a binding
17 requirement is subject to disciplinary action, and manufacturers are instructed to contact the staff

18 ("Industry, consumers and other stakeholders play a significant role in the agency's guidance
19 development processes... Draft proposals can help the agency better understand stakeholder positions,
20 particularly if the subject involved deals with novel scientific issues... The agency also invites the public
21 to comment on its draft Level 1 guidances and reviews and considers the submitted comments in
preparing the final documents."). A copy of this FDA Fact Sheet is attached as Exhibit L to the
accompanying RJN.

22 ⁶ For instance, the Grocery Manufacturers Association (GMA), the leading trade association for food and
23 beverage manufacturers, commented that the 2009 Draft Guidance was inconsistent with decades of
24 industry practice. And companies that made and sold ECJ noted that the replacement name for ECJ
25 suggested by the 2009 Draft Guidance—"dried cane syrup"—would actually be a less accurate name for
this sweetener because there is no "syrup" phase in the production of ECJ. See FDA, Docket Folder,
Ingredients Declared as Evaporated Cane Juice, at <https://www.regulations.gov/docket?D=FDA-2009-D-0430>.

26 ⁷ See FDA, Proposed Regulations and Draft Guidances, at [http://www.fda.gov/ScienceResearch/](http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/ProposedRegulationsandDraftGuidances/default.htm)
27 [SpecialTopics/RunningClinicalTrials/ProposedRegulationsandDraftGuidances/default.htm](http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/ProposedRegulationsandDraftGuidances/default.htm) (last updated
August 2, 2016). A copy of this page is attached as Ex. M to the accompanying RJN.

1 person's supervisor or the Agency's ombudsman should this occur. *See id.* § 10.115(o).

2 Moreover, for the avoidance of doubt, FDA expressly stated—on the face of the 2009
3 Draft Guidance itself—that “FDA’s guidance documents, including this guidance, do not
4 establish legally enforceable responsibilities.” (*See* RJN, Ex. A at 3.) The 2009 Draft Guidance
5 further stated that the “use of the word *should* in Agency guidances means that something is
6 suggested or recommended, ***but not required.***” *Id.*

7 **3. FDA had not settled on a uniform national enforcement policy.**

8 Even though FDA guidance documents are not binding or enforceable, FDA can—and
9 often does—encourage manufacturers to comply with a draft guidance on a voluntary basis. One
10 way FDA can usually obtain such voluntary compliance is by sending a “warning letter” to
11 companies, threatening legal action unless they modify their labels. *See Holistic Candles &*
12 *Consumers Ass’n v. FDA*, 664 F.3d 940, 944 (D.C. Cir. 2012) (explaining that warning letters are
13 “the agency’s principal means of achieving prompt voluntary compliance”). Even when FDA’s
14 position in a warning letter is factually inaccurate or legally suspect, recipients of warning letters
15 often implement the changes FDA requests to avoid a public dispute with the Agency.

16 FDA issued several warning letters that referenced the 2009 Draft Guidance.⁸ But FDA’s
17 decision to send warning letters over an issue covered by a draft Level 1 guidance does not
18 change the legal status of the guidance or suggest that it is a binding requirement. In fact,
19 warning letters do “not necessarily represent the formal position of FDA, and [do] not bind or
20 otherwise obligate or commit the agency to the view expressed.” *See* 21 C.F.R. § 10.85(k).
21 Rather, like draft Level 1 guidance documents, warning letters are “informal” and “advisory.”
22 *Id.*; *Biotics Research Corp. v. Heckler*, 710 F.2d 1375, 1378 (9th Cir. 1983) (FDA warning
23 letters are not binding or final and “do not commit the FDA to enforcement action”); *Holistic*
24 *Candles*, 664 F.3d 940, 944-45 (D.C. Cir. 2012) (FDA warning letters “do not represent final

25
26 ⁸ Odwalla received a letter from FDA concerning ECJ in 2012, which FDA designated an “untitled letter”
27 rather than a warning letter. It was in response to this letter that Odwalla notified FDA of its decision to
voluntarily discontinue its ECJ labeling. (Dkt. No. 65.)

agency action,” bear no legal consequences, and “plainly do not mark the consummation of FDA’s decision making”); *Dietary Supplemental Coalition, Inc. v. Sullivan*, 978 F.2d 560, 563 (9th Cir. 1992) (same).

After several failed attempts to obtain voluntary compliance with the 2009 Draft Guidance, FDA in 2014 published a Notice in the Federal Register announcing that the Agency was entirely reopening its regulatory process on ECJ. (*See* RJN, Ex. C.) In the Notice, FDA made clear that the Agency had *not* conclusively determined that federal law prohibits ECJ: “We have ***not reached a final decision*** on the common or usual name for this ingredient.” *Id.* at 1 (emphasis added). FDA also reiterated that the 2009 Draft Guidance was not the Agency’s official interpretation of federal law, but merely reflected the Agency’s “***preliminary thinking.***” *Id.* at 2 (emphasis added). The Notice stated that FDA needed “further comments, data, and information” regarding, *inter alia*, “the basic nature and characterizing properties of the ingredient,” “how this ingredient is produced,” and “how it compares with other sweeteners” in order to make a final determination. *Id.* at 1, 3.

D. The Court’s Motion to Dismiss Ruling

On March 25, 2014, three weeks after FDA reopened its regulatory process on ECJ, the Court granted Odwalla’s motion to dismiss on primary jurisdiction grounds. *Reese*, 30 F. Supp. 3d at 942. The Court recognized that, at bottom, “Plaintiff’s claims here are state law claims based upon the Sherman Law’s incorporation of the FDCA’s labeling requirements related to standards of identity and use of an ingredient’s common and usual name.” *Id.* at 941. “[W]hether ECJ is the ‘common and usual name’ for this ingredient,” however, “is a matter that is not only within the expertise and authority of [FDA], it is before the agency at this moment.” *Id.* The Court determined that the case should be stayed pending the outcome of FDA’s regulatory process.

The Court did not reach Odwalla’s other grounds for dismissal. In fact, the Court expressly left “aside the question of whether the Court can properly determine, in the first instance, if ECJ is or is not the ‘common and usual name’ of this ingredient[.]” *Id.* at 942. But

1 the Court made several findings relevant to the instant motion. First, the Court recognized that
 2 federal law as it relates to ECJ was “unsettled.” *Id.* at 939. Second, the Court found that the
 3 2009 Draft Guidance, which was the crux of Plaintiff’s case, was “non-binding” and “not legally
 4 enforceable” as a matter of federal law. *Id.*

5 Third, and importantly, the Court observed that Plaintiff’s “claims turn, first and
 6 foremost, on whether they are ‘misleading’ in the sense that they are considered ‘misbranded’
 7 under the federal food labeling laws, not on whether the labels are misleading in a general legal
 8 sense.” *Id.* at 942. “This is because the determination whether [a] label is misleading is
 9 governed entirely by its compliance with federal regulations in this area.” *Id.* Indeed, as the
 10 Court correctly noted, federal law “completely displaces any non-identical requirements in the
 11 areas governed by federal requirements” because the FDCA preempts any state requirement that
 12 “imposes obligations or contains provisions . . . that . . . are not imposed by or contained in the
 13 applicable” federal statute or regulations. *Id.*

14 **E. FDA’s 2016 Final Guidance**

15 On May 25, 2016, after more than two years of deliberations, FDA published the 2016
 16 Final Guidance and advised manufacturers that the Agency had concluded that “the term
 17 ‘evaporated cane juice’ is not the common or usual name of any type of sweetener.” (*See* RJN,
 18 Ex. B at 3.) But in a departure from the 2009 Draft Guidance, which had recommended that ECJ
 19 be labeled as “dried cane syrup,” the 2016 Final Guidance recommended that ECJ be “declared
 20 on food labels as ‘sugar[.]’” *Id.* at 5. As noted above, Odwalla did not need to change any of its
 21 labels in response to the 2016 Final Guidance because it had already phased out ECJ labels in
 22 2014. (*See* Dkt. No. 72.)

23 **ARGUMENT**

24 To avoid dismissal under Rule 12(b)(6), a plaintiff must plead facts sufficient to state a
 25 claim for relief that is plausible on its face. *See Davis v. Capitol Record, LLC*, No. 12-cv-1602
 26 YGR, 2013 U.S. Dist. LEXIS 55917, at *4 (N.D. Cal. April 18, 2013). While factual allegations
 27 must be taken as true, “conclusory statements not supported by actual factual allegations need
 28

not be accepted,” *id.*, and dismissal is warranted in the absence of a viable legal theory, *see Collings v. Teamsters Benefit Trust*, No. 12-cv-2984 YGR, 2013 U.S. Dist. LEXIS 49752, at *5 (N.D. Cal. April 5, 2013). Rule 12(b)(6) also allows courts to dismiss claims for unsustainable forms of relief. *See Whittlestone, Inc. v. Handi-Craft Co.*, 618 F.3d 970, 973 (9th Cir. 2010).

Odwalla discontinued its ECJ labeling in 2014, and there were no Odwalla products labeled with ECJ on the market when FDA published the 2016 Final Guidance. The only question presented in this case, therefore, is whether Plaintiff’s claims with regard to Odwalla products sold prior to 2014—when Plaintiff made her purchases and filed her Complaint—are viable. As the Court has already found, the requirements of federal law as it relates to ECJ were unsettled at that time, and FDA’s only pronouncement on the subject—the 2009 Draft Guidance—was not binding or legally enforceable. Plaintiff’s claims, therefore, fail as a matter of both California and federal law. Plaintiff’s monetary claims should be dismissed, and her claim for injunctive relief deemed moot.

I. CALIFORNIA LAW DOES NOT INCORPORATE NON-BINDING FDA GUIDANCE DOCUMENTS, SUCH AS THE 2009 DRAFT GUIDANCE

In its prior motion to dismiss ruling, the Court recognized that Plaintiff’s state-law claims are predicated on Plaintiff’s central allegation that Odwalla’s ECJ labeling violated California’s Sherman Act:

Plaintiff’s claims here are state law claims based upon the Sherman Law’s incorporation of the FDCA’s labeling requirements related to standards of identity and use of an ingredient’s common and usual name.

Reese, 30 F. Supp. 3d at 941. As such, the Court recognized that the “viability of Plaintiff’s claims turns on the question of whether the FDA [had] determined, as Plaintiff alleges, that the use of the term ECJ is ‘unlawful’” under federal law. *Id.* at 939. This is because, in order to prove a violation of the Sherman Law, a Plaintiff must establish that federal law was violated.

According to the Complaint, Odwalla’s ECJ labeling violated federal law because the 2009 Draft Guidance declared ECJ unlawful and required this ingredient to be labeled as something different. (Compl. ¶¶ 41, 47.) According to its plain statutory text, however, the

Sherman Law incorporates only binding FDA “food labeling *regulations*” as “the food labeling regulations of this state.” Cal. Health & Saf. Code § 110100; *see also In re Farm Raised Salmon Cases*, 42 Cal. 4th 1077, 1087 (Cal. 2008) (“California has adopted as its own the FDA regulations” regarding food labeling). The 2009 Draft Guidance on ECJ was not a binding regulation.

The California legislature clearly did not intend to make every draft FDA policy or preliminary position statement the law of the state. Indeed, since draft Level 1 guidance documents may be published by FDA without prior notice or public comment, it would raise serious Due Process concerns if California were to make them *automatically* binding under state law, potentially exposing companies to huge financial liability without warning. *See Louis v. United States Dept. of Labor*, 419 F.3d 970, 975 (9th Cir. 2005) (acknowledging that the notice-and-comment procedures for agency rulemaking are necessary to protect the Due Process rights of the regulated community); *United States v. AMC Entm’t, Inc.*, 549 F.3d 760, 770 (9th Cir. 2008) (retroactive application of a regulatory clarification of existing law contravenes Due Process). The Sherman Law avoids this constitutional concern by making only final, binding regulations the law in California. *Cf. Wilson v. Frito-Lay N. Am.*, 961 F. Supp. 2d 1134, 1140, 1147 (N.D. Cal. 2013) (recognizing, in the context of a Sherman Law case, that it would violate Due Process to allow claims under California law based upon informal positions FDA had taken in warning letters).

It would contradict the plain language of the Sherman Law to allow Plaintiff to enforce the 2009 Draft Guidance through California law. Plaintiffs’ claims must be dismissed for this reason alone.

II. PLAINTIFF IS EXPRESSLY PREEMPTED FROM SEEKING TO IMPOSE REQUIREMENTS THAT FEDERAL LAW DID NOT IMPOSE AT THE TIME OF HER PURCHASES

Even if California law purported to authorize private plaintiffs to enforce FDA’s non-binding, draft guidance documents, Congress has expressly preempted such claims through the

1 Nutrition Labeling and Education Act (NLEA) of 1990. The Court correctly described the legal
2 framework for NLEA preemption in its prior motion to dismiss ruling:

3 [Plaintiff’s] claims turn, first and foremost, on whether they are ‘misleading’ in
4 the sense that they are considered ‘misbranded’ under the federal food labeling
5 laws, not on whether the labels are misleading in a general legal sense. This is
6 because the determination whether [the] label is misleading is governed entirely
7 by its compliance with the federal regulations in this area. Federal law
8 completely displaces any non-identical requirements in the areas covered by
9 federal requirements. 21 U.S.C. §§ 343-1(a)(1)-(5)[.]⁹

10 . . .

11 [N]o state may establish any requirement that is not identical to a standard of
12 identity established under 21 U.S.C. § 341 or 343(g) or any requirement for the
13 labeling of the type required in any of a number of enumerated sections of section
14 343 that is not identical to that requirement[.]

15 . . .

16 [A] state requirement is preempted if it not identical to the federal provision,
17 meaning that the state provision differs from the federal or that the state provision
18 ‘imposes obligations *or contains provisions . . . that . . . are not imposed* by or
19 contained in the applicable [federal statute or regulation].

20 *Reese*, 30 F. Supp. 3d at 942 (emphasis in original); *see also Turek v. Gen. Mills, Inc.*, 662 F.3d
21 423, 427 (7th Cir. 2011) (“consistency is not the test; identity is.”). Preempted requirements
22 include those “of the type” specified in 21 U.S.C. § 343(i), which governs common and usual
23 names. *See* 21 U.S.C. § 343-1(a). Applying this framework to the allegations in this case leaves
24 no doubt that Plaintiff’s state-law claims are preempted.

25 At the time that Plaintiff made her purchases, federal law did not require manufacturers
26 to label ECJ by some other name, and thousands of products sold throughout the country bore

27 ⁹ Here, the Court’s citation is to the NLEA’s express preemption clause, which mandates in full that:
28 no State or political subdivision of a State may directly or indirectly establish under any
authority or continue in effect as to any food in interstate commerce . . . any requirement
for the labeling of food of the type required by . . . [among others, Section 343(i)] . . . that
is *not identical* to the requirement of such section.

21 U.S.C. § 343-1(a) (emphasis added).

1 ECJ labeling. Moreover, FDA had chosen not to issue a binding requirement that products
 2 containing ECJ be relabeled, but instead published the 2009 Draft Guidance to spur further
 3 discussion between the Agency and the regulated community. The NLEA's express preemption
 4 clause bars Plaintiff from seeking to impose, through her state-law claims, a requirement that
 5 federal law at the time did not. *See Carrea v. Dreyer's Grand Ice Cream, Inc.*, 475 F. App'x
 6 113, 115 (9th Cir. 2012) (holding plaintiff was expressly preempted from imposing labeling
 7 requirements for trans fat that did not exist under federal law); *see also Perez v. Nidek Co.*, 711
 8 F.3d 1109, 1118-19 (9th Cir. 2013) (finding claim expressly preempted because plaintiff
 9 "effectively [sought] to write in a new provision to the FDCA").¹⁰

10 FDA's 2016 Final Guidance does not change this analysis. As discussed above, by the
 11 time FDA published the 2016 Final Guidance, no Odwalla products were labeled with ECJ. The
 12 legal effect of the 2016 Final Guidance—and whether it enables plaintiffs to pursue claims
 13 against products *currently* labeled with ECJ—is therefore not a question that the Court must
 14 decide in this case. The only question is whether the 2016 Final Guidance somehow renders the
 15 NLEA's preemption clause inoperable and retroactively imposes a binding requirement during
 16 the pre-2014 time period, when Plaintiff made her purchases and no such requirement was in
 17 effect. It does not, and Plaintiff's claims are therefore expressly preempted.

18 Three recent decisions from courts in California make this precise point. *See Wilson v.*
 19 *Frito-Lay N. Am.*, 961 F. Supp. 2d 1134, 1147 (N.D. Cal. 2013); *Peterson v. Conagra Foods,*
 20 *Inc.*, No. 13-cv-3158-L (NLS), 2014 U.S. Dist. LEXIS 104073, at *12 (S.D. Cal. July 29, 2014);
 21 *Eckler v. Neutrogena Corp.*, 238 Cal. App. 4th 433, 189 Cal. Rptr. 3d 339 (2015). In *Wilson* and
 22 *Peterson*, plaintiffs filed suit against two food companies challenging "No MSG" claims on
 23 product labels after FDA in November 2012 published a guidance on its website stating that "No
 24 MSG" claims were not permitted if a food contains ingredients that may themselves contain

25
 26 ¹⁰ *See also Bronson v. Johnson & Johnson, Inc.*, No. C 12-04184 CRB, 2013 U.S. Dist. LEXIS 54029, at
 27 *11-12 (N.D. Cal. April 16, 2013); *Chacanaca v. Quaker Oats Co.*, 752 F. Supp. 2d 1111, 1118-23 (N.D.
 28 Cal. 2010); *Peviani v. Hostess Brands, Inc.*, 750 F. Supp. 2d 1111, 1119-20 (C.D. Cal. 2010)

1 MSG. The *Wilson* court held that the plaintiff's claims were *not* preempted as to products
2 labeled with "No MSG" *after* November 2012 when FDA published its guidance. 961 F. Supp.
3 2d at 1147. But the court held the opposite as to products sold *before* November 2012 because,
4 at that time, FDA's interpretation of federal law—which had been expressed in informal policy
5 statements and warning letters to companies—was "ambiguous." *Id.*

6 As the *Wilson* court explained, "To insist that Defendant should have been complying
7 with a regulation that was not explicitly clarified until" November 2012 "would buck due
8 process and Ninth Circuit precedent" barring enforcement of non-final federal requirements. *Id.*
9 The *Peterson* court subsequently reached the same conclusion: "FDA's November 2012
10 [s]tatement regarding MSG clarified an ambiguous regulation. . . . Because the labeling
11 requirement imposed by state law is not identical to the FDA regulations before November 19,
12 2012, federal law preempts [plaintiff's'] claims before" that date. 2014 U.S. Dist. LEXIS
13 104073, at *12.

14 *Eckler* is to the same effect. There, the plaintiff sued under California law challenging
15 "sunblock," "waterproof," and "sweatproof" claims on labels for the defendant's sunscreen
16 products after FDA published a Final Rule in June 2011 requiring sunscreen makers to
17 discontinue such claims by December 2012. 238 Cal. App. 4th at 456. The California appeals
18 court held that the plaintiff's claims were preempted because, although FDA for years had raised
19 significant concerns about these claims, FDA did not definitively interpret federal law to prohibit
20 them "until the publication of the Final Rule on June 17, 2011," after which the defendant
21 discontinued the claims. *Id.*

22 *Wilson*, *Eckler*, and *Peterson* apply with equal force here. As in these cases, Plaintiff's
23 claims are expressly preempted for the time period when the requirements of federal law were
24 unsettled, and FDA's subsequent clarification of the law does not change this analysis. And
25 here, as in *Eckler*, Plaintiff has no claims based on conduct that post-dates FDA's clarification of
26 the law, so Plaintiff's claims are preempted in their entirety.

III. PLAINTIFF'S ARGUMENTS AGAINST DISMISSAL ALL FAIL

In opposition to Odwalla's original motion to dismiss, and in multiple submissions to the Court in the years since, Plaintiff has repeatedly asserted the same arguments for keeping her claims alive. All of these arguments fail.

First, Plaintiff has argued that FDA has "continuously and consistently" disapproved of ECJ as a common and usual name. (*See, e.g.*, Dkt. No. 85 at 1.) But under California's Sherman Law and the NLEA, the dispositive question is not whether FDA's views have been consistent, but whether FDA's views constituted a final, binding requirement under federal law. The Court answered this question in its prior motion to dismiss ruling when it determined that federal law concerning ECJ, even as of the time of that ruling, was "unsettled," and that FDA's views expressed in the 2009 Draft Guidance and subsequent warning letters were "non-binding" and "not legally enforceable." *Reese*, 30 F. Supp. 3d at 939.

Second, Plaintiff has argued that, notwithstanding the Complaint's heavy reliance on the 2009 Draft Guidance, she is actually seeking to enforce the FDCA's general common and usual name provisions and the standard of identity for sugar, which predate the 2009 Draft Guidance. (*See, e.g.*, Dkt. No. 85 at 4.) As this Court has observed, however, Congress's goal in enacting the NLEA was to "creat[e] a uniform national scheme of regulation to ensure that food is labeled" appropriately. *Reese*, 30 F. Supp. 3d at 941. It would undermine Congress's intent, and gut the NLEA's preemption clause, if private plaintiffs could invoke *general* FDCA provisions to create *specific* requirements that FDA is in the process of debating, and has expressly declined adopt.

Indeed, similar attempts to fall back on general FDCA requirements to circumvent preemption were rejected in the *Wilson*, *Peterson*, and *Eckler* cases discussed above. In all three cases, the plaintiffs argued that the defendants' labels violated existing FDA requirements akin to the common and usual name requirement or the standard of identity of sugar that Plaintiff has invoked here. The *Wilson* and *Peterson* defendants were alleged to have violated, *inter alia*, 21 C.F.R. § 101.22(h)(5) (common and usual name) and 101.22 (labeling of spices). *See Peterson*,

1 2014 U.S. Dist. LEXIS 104073, at *8; Second Amended Class Action Complaint, *Wilson v.*
 2 *Frito-Lay N. Am.*, No. 3:12-cv-01586-JST, Dkt. No. 47 (N.D. Cal. May 1, 2013).¹¹ The *Eckler*
 3 defendants were alleged to have violated FDA's monograph for sunscreen products. *Eckler*, 238
 4 Cal. App. 4th at 455-56.

5 Moreover, in all three cases, the plaintiffs argued that their claims escaped preemption
 6 because the federal requirements that defendants allegedly violated "had been in place for
 7 decades" before their complaints were filed. *Wilson*, 961 F. Supp. 2d at 1146; *Peterson*, 2014
 8 U.S. Dist. LEXIS 104073, at *12; *Eckler*, 238 Cal. App. 4th at 454 ("FDA banned the use of the
 9 terms long before" a final rule was published). The courts flatly rejected this argument.
 10 Although the FDCA provisions had been on the books for years, the plaintiffs' claims
 11 nevertheless were preempted because FDA's interpretation of these regulations, at least with
 12 respect to the label statements disputed in those cases, was unsettled. Exactly the same is true
 13 here.

14 ***Third***, in a variant of the same argument, Plaintiff has asserted that she is seeking to
 15 enforce the FDCA's general prohibition in section 403(a) of the statute against labels that are
 16 "false or misleading in any particular." (*See, e.g.*, Dkt. No. 85 at 4.) Not surprisingly, courts
 17 have rejected such attempts to invoke the FDCA's general misbranding provisions in this
 18 manner.

19 For example, in *Gorenstein v. Ocean Spray Cranberries, Inc.*, No. 09-5925 GAF, 2010
 20 U.S. Dist. LEXIS 143801 (C.D. Cal. Jan. 29, 2010), the plaintiff challenged the name and label
 21 of an Ocean Spray juice product and sought to impose disclosure requirements that FDA had
 22 previously considered and chosen not to implement. Notwithstanding FDA's prior
 23 determination, the plaintiff argued that her claims were not preempted because Ocean Spray's
 24 label violated the FDCA's *general* prohibition against "false or misleading" labels, and that she
 25 was entitled to enforce this "identical" requirement through his state-law claims. *Id.* at *1-2.

26 ¹¹ *See* Complaint, *Peterson v. Conagra Foods, Inc.*, No. 13-cv-3158-L (NLS), Dkt. No. 13 (S.D.
 27 Cal. Mar. 10, 2014).

1 The court rejected this theory, recognizing that such an interpretation “would eviscerate [the
 2 NLEA’s] strict preemption requirements” and “defeat[] [its] statutory objective” that “federal
 3 law govern[] the content of [defendant’s] label[s]” and that “manufacturers should not be
 4 subjected to 50 different sets of labeling rules.” *Id.* at *3-5; *see also Backus v. Nestlé USA, Inc.*,
 5 No. C-15-1963 MMC, 2016 U.S. Dist. LEXIS 29669, at *20 n.8 (N.D. Cal. Mar. 8, 2016) (citing
 6 *Gorenstein*, 2010 U.S. Dist. LEXIS 143801) (“The Court finds unpersuasive Backus’s argument
 7 that his labeling claims nonetheless survive under 21 U.S.C. § 343(a), a general provision that
 8 precludes labeling that is ‘false or misleading in any particular’ and is not referenced in the
 9 express preemption provisions of § 343-1.”); *Red v. Kroger Co.*, No. 10-01025 DMG, 2010 U.S.
 10 Dist. LEXIS 115238, at *7-16 (N.D. Cal. Sept. 2, 2010) (rejecting plaintiff’s argument that his
 11 claims were “beyond the NLEA’s express pre-emption provision” because he premised liability
 12 on the FDCA’s general misbranding provisions); *Chavez v. Nestle USA, Inc.*, No. 09-9192-GW,
 13 2011 U.S. Dist. LEXIS 9773, at *25 (C.D. Cal. Jan. 10, 2011) (“Plaintiffs’ argument that the
 14 ‘False Or Misleading’ language of 21 U.S.C. § 343(a) defeats express [NLEA] preemption is
 15 unpersuasive.”).

16 Similar arguments have been presented to the Ninth Circuit and rejected in an NLEA
 17 preemption case. In *Carrea v. Dreyer’s Grand Ice Cream*, the plaintiff alleged that the
 18 defendant’s ice cream labels violated California law because they stated that the product had “0 g
 19 of Trans Fat” when, in fact, small amounts of trans fat were present. The district court held that
 20 this claim was preempted because federal regulations expressly permit trans fat in amounts less
 21 than 0.5 grams per serving to be “expressed as zero.” No. C 10-01044 JSW, 2011 U.S. Dist.
 22 LEXIS 6371, at *8-12 (N.D. Cal. Jan. 10, 2011). On appeal, the plaintiff argued that, FDA’s
 23 specific considerations notwithstanding, the FDCA prohibits labeling that is “false or misleading
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 25
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 27
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1 in any particular,” and that his state-law claim merely sought to impose requirements “identical
2 to [this] federal requirement[.]”¹²

3 The Ninth Circuit affirmed the district court’s dismissal order, agreeing that the plaintiff
4 was preempted from seeking “to enjoin and declare unlawful” a labeling practice that “federal
5 law permits.” 475 F. App’x at 115. The Ninth Circuit apparently thought so little of the
6 plaintiff’s attempt to elevate the general language of the FDCA over FDA’s specific regulations
7 that it did not find it worthy of discussion in its opinion. But the court’s holding necessarily
8 rejects the argument.¹³ The outcome should be no different here.

9 **Fourth**, Plaintiff has cited *Ivie v. Kraft Foods Global, Inc.*, No. C-12-02554-RMW, 2013
10 U.S. Dist. LEXIS 25615 (N.D. Cal. Feb. 25, 2013), for the proposition that state-law claims over
11 ECJ labeling are not preempted. The preemption issues specific to ECJ, however, were not
12 thoroughly briefed in that case, and the court’s reasoning is not persuasive. The court concluded
13 that the plaintiff’s claims in that case were not preempted because FDA’s position on ECJ was
14 “clear,” and express preemption does not bar claims under the UCL’s “deceptive” prong. *Id.* at
15 *36. Neither conclusion is correct.¹⁴

16 ¹² Appellant’s Reply Brief, No. 11-15263, 2011 U.S. 6th Cir. [sic] Briefs LEXIS 37, at *4-13 (9th Cir.
17 Oct. 28, 2011); *see generally* Appellant’s Initial Brief, No. 11-15263, 2011 U.S. 6th Cir. [sic] Briefs
18 LEXIS 38, at *20-29 (9th Cir. July 29, 2011).

19 ¹³ The Seventh Circuit rejected a similar argument in *Turek v. General Mills, Inc.* There, the plaintiff
20 alleged that the labeling of Fiber One Chewy Bars was misleading because the product contained “non-
21 natural” fiber and did not disclose that “non-natural” fiber is less beneficial than natural fiber. 754 F.
22 Supp. 2d 956, 956-57 (N.D. Ill. 2010). The district court dismissed the plaintiff’s claims as preempted by
23 the NLEA because FDA had specifically considered the purported differences between natural and “non-
24 natural” fiber and had chosen not to require the type of disclosure that plaintiff sought. On appeal, the
25 plaintiff invoked the FDCA’s general prohibition against false and misleading labeling. *See* Reply Brief
for Appellant at 4-5, No. 10-3267, Dkt. No. 20, (7th Cir. July 11, 2011). But the Seventh Circuit affirmed
the dismissal of the plaintiff’s claims, concluding that “[t]he disclaimers [about “non-natural” fiber] that
the plaintiff wants added” to Fiber One labels “are not identical to the labeling requirements imposed on
such products by federal law, and so they are barred.” 662 F.3d at 427. Like the Ninth Circuit in *Carrea*,
the Seventh Circuit did not dignify the plaintiff’s “general-trumps-the-specific” argument with a response,
but rejected it nonetheless.

26 ¹⁴ Before FDA reopened its regulatory process on ECJ, some district courts followed *Ivie*. *See, e.g.,*
27 *Leonhart v. Nature’s Path Foods, Inc.* No. 5:13-CV-0492-EJD, 2014 U.S. Dist. LEXIS 46413, at *19
(N.D. Cal. March 31, 2014); *Pratt v. Whole Foods Mkt. Cal. Inc.*, No. 5:12-CV-05652-EJD, 2014 U.S.
Dist. LEXIS 46409, at *16-17 (N.D. Cal. Mar. 31, 2014); *Werdebaugh v. Blue Diamond Growers*, No.

1 The *Ivie* decision was issued in 2013, and as this Court is well aware, FDA's position on
 2 ECJ at that time was far from "clear." In fact, the 2009 Draft Guidance did not even represent
 3 the FDA's official position or actual "thinking on this topic." (*See* RJN, Ex. A.) The *Ivie* court's
 4 apparent belief that plaintiffs can pursue claims under the "deceptive" prong of California's UCL
 5 without triggering preemption also was clearly incorrect. Regardless of the prong invoked,
 6 courts have consistently held that claims are expressly preempted when they would impose
 7 requirements that differ from federal law. *See Lam v. Gen Mills, Inc.*, 859 F. Supp. 2d 1097,
 8 1101-03 (N.D. Cal. 2012) (finding claims expressly preempted where the "crux" of the
 9 Complaint was that defendants' labeling was deceptive); *Dvora v. Gen. Mills, Inc.*, No. 11-1074-
 10 GW, 2011 U.S. Dist. LEXIS 55513, at *12-15 (C.D. Cal. May 16, 2011) (finding plaintiff's
 11 claims that "the phrase 'Naturally and Artificially Flavored' render[ed defendant's] product
 12 labeling both deceptive and non-compliant with federal regulations" preempted because they
 13 sought "to impose limitations . . . different from what federal regulations currently
 14 require/permit").

15 * * *

16 In sum, when Plaintiff made her purchases and filed this case, federal law did not
 17 conclusively prohibit ECJ labeling or require this ingredient to be labeled by a different name.
 18 Federal law was unsettled, and FDA had chosen to proceed with a non-binding guidance rather
 19 than impose a legally enforceable federal requirement. This is fatal to Plaintiff's claims, which
 20 fail under California's Sherman Law and preempted in any event. All of Plaintiffs' contrary
 21 arguments lack merit.

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 25 12-CV-02724-LHK, 2013 U.S. Dist. LEXIS 144178, at *29-31 (N.D. Cal. Oct. 2, 2013); *Kane v.*
 26 *Chobani, Inc.*, No. 12-CV-02425-LHK, 2013 U.S. Dist. LEXIS 98752, at *50-57 (N.D. Cal. July 12,
 27 2013). FDA's decision to reopen the regulatory process on ECJ, as well as FDA's clarification that the
 28 Agency had not determined the status of ECJ under federal law, demonstrates that these decisions were
 incorrect.

IV. PLAINTIFF'S CLAIMS FOR INJUNCTIVE RELIEF SHOULD BE DISMISSED

Plaintiff may argue that, even if her claims for monetary relief are dismissed, her request for an injunction should survive. Any such argument would fail as a matter of law.

As this Court has already found, it is undisputed that Odwalla “previous[ly] remov[ed] . . . the term ‘evaporated cane juice’ from” its labels. (Dkt. No. 72.) Under well-established Supreme Court precedent, Plaintiff must demonstrate the existence of an Article III case or controversy “separately for each form of relief sought.” *DaimlerChrysler Corp. v. Cuno*, 547 U.S. 332, 352 (2006). For purposes of injunctive relief, Article III requires “a real and immediate threat” that Plaintiff “will again be wronged” by Odwalla “in a similar way.” *City of Los Angeles v. Lyons*, 461 U.S. 95, 102-03, 111 (1983). There is no such threat here, and Plaintiff’s claims for injunctive relief at minimum should be dismissed as moot.

“[A] case is moot when the issues presented are no longer ‘live’ or the parties lack a legally cognizable interest in the outcome.” *City of Erie v. Pap’s A.M.*, 529 U.S. 277, 287 (2000) (citations and internal quotations omitted). Mootness “can be described as the doctrine of standing set in a time frame: The requisite personal interest that must exist at the commencement of the litigation (standing) must continue throughout its existence (mootness).” *Friends of the Earth, Inc. v. Laidlaw Envtl. Servs. (TOC), Inc.*, 528 U.S. 167, 189 (2000).

When the conduct challenged in a lawsuit has completely ceased, any previously existing threat of future harm is, by definition, no longer “real and immediate.” Any Article III case or controversy as to injunctive relief therefore evaporates. *See Beaulieu v. Ludeman*, 690 F.3d 1017, 1024 (8th Cir. 2012) (“[A] pending claim for injunctive relief becomes moot when the challenged conduct ceases and there is no reasonable expectation that the wrong will be repeated.”); *Outdoor Media Grp., Inc. v. City of Beaumont*, 506 F.3d 895, 902 (9th Cir. 2007) (claim for injunctive relief was moot where plaintiff could not show “that the challenged conduct continues”). Because Odwalla products labeled with ECJ no longer exist, this case presents a textbook example of mootness. *See Bronson v. Johnson & Johnson, Inc.*, No. C 13-04184 CRB,

1 2013 U.S. Dist. LEXIS 54029, at *5 n.2 (N.D. Cal. Apr. 16, 2013) (discontinuation of the
2 challenged labeling “renders moot Plaintiffs’ request for injunctive relief related to those
3 products”); *Peyser v. Searle Blatt & Co.*, No. 99-cv-10785 (WK), 2000 U.S. Dist. LEXIS 10793,
4 at *13 (S.D.N.Y. Aug. 3, 2000) (“[W]e must . . . dismiss the injunctive relief claim against Searle
5 as moot, because Searle no longer sells [the] infringing clothes.”).

6 Plaintiff cannot circumvent this jurisdictional impediment by invoking the “voluntary
7 cessation” exception to mootness doctrine and arguing that Odwalla is theoretically “free to
8 return to [its] old ways.” *United States v. W. T. Grant Co.*, 345 U.S. 629, 632-33
9 (1953). Odwalla has not labeled its products with ECJ for years and has no plans to do so again.
10 Moreover, in light of the 2016 Final Guidance, Odwalla would be constrained from doing so.
11 The “voluntary cessation” doctrine, therefore, does not apply in this case. *See Rosebrock v.*
12 *Mathis*, 745 F.3d 963, 971 (9th Cir. 2014) (voluntarily cession does not trump mootness when it
13 is “absolutely clear” that the disputed conduct will not resume); *see also Smith v. Univ. of Wash.*
14 *Law Sch.*, 233 F.3d 1188, 1195 (9th Cir. 2000) (recognizing that “[t]here can be no real
15 expectation that the alleged wrongs will recur” when a change in the law constrains the
16 defendant from engaging in the conduct); *Lindquist v. Idaho State Bd. of Corrs.*, 776 F.2d 851,
17 854 (9th Cir. 1985) (claim for injunctive relief moot where the defendant “in good faith” sought
18 to address the concern and there was “no indication” that defendant would “abandon its efforts”).
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CONCLUSION

For all of the forgoing reasons, the Complaint should be dismissed, in its entirety, with prejudice.

DATE: August 10, 2016

Respectfully submitted,

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